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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,883	09/23/2003	John Paul Maye	50557-11	3592
21874	7590	12/20/2004	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			FLOOD, MICHELE C	
			ART UNIT	PAPER NUMBER
			1654	
DATE MAILED: 12/20/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,883

Applicant(s)

MAYE, JOHN PAUL

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, Claims 6-12, in the reply filed on December 1, 2004 is acknowledged. Claims 1-5 and Claims 13-16 are withdrawn from further consideration as a group drawn to a non-elected invention.

Claims 6-12 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "the hop acids" in line 1. There is a lack of clear antecedent basis for this limitation in the claim. Applicant may overcome the rejection by replacing "hop acids" with hop acid.

With regard to Claim 8, there is an apparent misspelling in line 1. Applicant should delete "on", and add one.

Claim 12 recites the limitation "the hop acid capable of increasing the level of propionate" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

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All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krishna et al. (U), as evidenced by Newmark et al. (A), Muller (N), and Haas et al. (C) in view of Hunter et al. (B) and Johnson et al. (O).

Applicant claims a method for increasing food intake and energy uptake from a livestock feed by livestock comprising administering to the livestock a feed having an effective amount of hop acid capable of decreasing the production of unoxidized carbon sources in a digestive system fluid of the livestock. Applicant further claims the method of claim 6, wherein the hop acid is selected from at least one of a group consisting of alpha acids, beta acids, isoalpha acids, rho-isoalpha acids, tetrahydroisoalpha acids and hexahydroisoalpha acids. Applicant further claims the method of claim 7, wherein the alpha acids are selected from at least one of the group consisting of humulone, cohumulone, and adhumulone; and, wherein the beta acids are selected from at least one of the group consisting of lupulone, colupulone, and adlupulone. Applicant further

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claims the method of claim 6, wherein the amount of hop acid is 2 ppm of digestive system fluid; and, wherein the livestock is selected from the group consisting of cattle, poultry, horses, pigs, and zoo animals. Applicant further claims the method of claim 1 further comprising administering a hop acid capable of increasing the level of propionate in the digestive system fluid.

Krishna discloses the results of two long-term experiments, which studied the effects of diets consisting of preparation of spent hops and apple pomace in simulated rumen fermentation. For instance, Krishna teaches, "The spent hops preparations were: (H1) hops extracted with CH_2Cl_2 , (H2) hops extracted with hot water, (H3) treatment with supercritical CO_2 at 45-50° up to 400 atm pressure, (H4)-mechanical sifting of hop powder at -35°. The diet containing H3 gave markedly lower CH_4 output, a slight increase in propionic acid, and a marked decrease in HOAc per unit dry matter digested. The amounts of hexose used and the recovery of H2 were low in H3-complete diet. Addition of apple pomace to basal diets of hay, H3, or their mixture only resulted in a marked overall decrease in N and dry matter digestibility. Preparation H2 had highest lignin and lowest degradable cell wall contents (resistant to 3% alkali and NH_3) and, in Rusitec, had the lowest digestible N and dry matter. Spent hop preparations H1 and H4 appear to have the greatest potential as animal feed components. A significant increase in total volatile fatty acids and CH_4 production was observed when any spent hop preparation was incubated in separate bags rather than in mixtures with other components."

The Office notes that Krishna does not expressly teach that the spent hops used in the experimental studies comprised the instantly claimed ingredients of hop acids. However, the Office deems that the instantly claimed ingredients are inherent to the spent hops extracts taught by Krishna, as evidenced by the teachings of Newmark, Muller and Haas. Firstly, Newmark teaches that a supercritical carbon dioxide extract of hops comprises alpha acids, *i.e.*, humulones; and, beta acids, *i.e.*, lupulones, in Column 6, lines 27-31. Secondly, in Column 1, lines 43-54, Muller teaches that alpha acids, such as humulones, and beta acids, such as lupulones, are inherent components of spent hops. Muller further teaches a process for obtaining lupulones or hulupones from lupulones from hop extracts by treatment with supercritical carbon dioxide under a reduced pressure. Thirdly, Haas also teaches that hop resins or hop acids (both alpha acids and beta acids) can be obtained from the hop plant by supercritical critical carbon dioxide treatment, in Column 1, lines 1-41. Haas further teaches that treating hop acid extracts with carbon dioxide greatly improves the killing activity of alpha acids, *e.g.*, humulone, isoalpha acids, and tetraisoalpha acids, and beta acids, *e.g.*, xanthohumol for protozoa. As Krishna teaches that H3 was obtained by treatment with supercritical carbon dioxide, the H3 taught by Krishna is deemed to inherently comprise the instantly claimed alpha acids and beta acids.

The teachings of Krishna are set forth above. Krishna does not teach a method for increasing food and energy uptake from a livestock feed by livestock comprising administering to the livestock any of the referenced spent hop extracts. However, it would have been obvious to one of ordinary skill in the art to administer an effective

amount of the livestock feed taught by Krishna, namely H3, to livestock to provide the instantly claimed method because Krishna teaches that the administration of the referenced supercritical spent hops extract to a simulated rumen digestion system had the beneficial effect for markedly reducing the production of unoxidized carbon sources, *i.e.*, methane, and an increase in propionic acid. Since Krishna teaches that the referenced spent hops extract markedly lowered methane output and increased the production of propionic acid, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to administer an effective amount of the livestock feed taught by Krishna to a livestock animal to provide the instantly claimed method because at the time the invention was made it was known in the art that a decrease in methane output and an increase in propionic acid production in a digestive system fluid of a livestock indicates a shift in the microbial population of microorganisms normally residing in the rumen of livestock. For instance, in Column 14, lines 22-36, Hunter teaches, "The biologically-active copolymers can also be added to cattle feed to effect a change in the population of microorganisms normally resident in the rumen. Under normal conditions, the microorganisms digest the cellulose that is eaten by the cattle to the end-product methane. Methane is essentially unusable by the cattle. By administering the biologically-active copolymers of the present invention orally to the cattle, the copolymer differentially affects the rumen population of microorganism resulting in an increase in propionic acid production and a decrease in lactic acid and methane. Cattle are capable of using propionate in their own metabolism thereby increasing the efficiency of food conversion." Thus, the claimed

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invention is no more than the administration of well-known ingredients to livestock known in the art for having the beneficial effect of increasing food and energy uptake of livestock feed by decreasing the production unoxidized carbon sources and increasing the level of propionate in the digestive fluid of an animal as a result-effective variable in shifting the residence population of microorganisms present in the digestive fluid of an animal, as evidenced by the aforementioned references.

With regard to Claim 10 wherein Applicant directs the method of claim 6 to wherein the amount of hop acid is 2 ppm of digestive system fluid, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and one would have had a reasonable expectation of success to optimize the amounts of the hop acids administered in the method of treatment taught by Krishna because Krishna teaches that the administration of the instantly claimed ingredients have the beneficial effect for decreasing the production of unoxidized carbon sources and increasing the level of propionate in rumen and suggests using the hop acid extracts as livestock feed. It also would have been obvious to provide the instantly claimed amounts of the spent hops extracts taught by Krishna in the instantly claimed amounts in the digestive system of an animal, and one would have been further motivated and had a reasonable expectation of success to provide the instantly claimed amounts of hop acids in the digestive system of an animal because at the time the invention was made Johnson taught that supercritical carbon dioxide extracts of hops in the claim-designated amounts provide protection against *Clostridium*

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spp. and that incorporation of upper levels of beta acids to an oral composition is dictated by taste and solubility of a food product, on page 4, lines 12-19.

As the references indicate that the various proportions and amounts of the ingredients used in the claimed method of treatment are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.


* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHELE FLOOD
PATENT EXAMINER
MCF
December 13, 2004